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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,627	05/31/2000	JEAN-GERARD GUILLET	97AECNRIMM	7512
23869	7590	11/26/2003		
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/403,627	Applicant(s) GUILLET ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED                      FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 10 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 21, 56-60 and 104-110.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: See Continuation Sheet

Continuation of 10. Other: Applicant argues that peptides that bind to MHC can be approximately nine amino acids in length and that it would not cause undue experimentation to test only 255 possible peptide analogs containing at least one peptide bond replacement. Applicant is arguing limitations which are not in the claims and the calculation does not accurately reflect the number of possible differences. The term "at least one" is a lower limit only. The upper extremity conveyed by that term is limited only by the number of peptide bonds in the molecule, or one less than the number of residues in the peptide. Further, the claims encompass ANY type of mutation to the bond between adjoining amino acid residues. Using just the 9-mer example cited by Applicant and the 19 mutations disclosed in the specification (page 6, line 23 to page , line 13 for example), there are 20 different possible bonds (including the normal CO-NH) at each of the eight bond positions within the 9-mer, giving rise to 8 to the 20th, or more than  $1.15 \times 10$  to the 18th different possible peptides. Unlike the 255 possibilities alleged by Applicant, testing of said number of variants of just a single nonamer does not amount to routine experimentation. It is further notable that the claims also encompass the substitution of "at least one" amino acid of the parent peptide chain with a "non-protein-generating amino acid." Said term is defined on page 4 of the specification (lines 5-11) as "any amino acid which is not involved in the construction of a natural peptide or protein." This definition not only includes any and all amino acid residues which are not naturally occurring residues, but also includes all mimetic molecules which could be substituted for a natural amino acid residue in a peptide sequence and, in its broadest sense, also includes any 'natural' amino acid residue that is substituted into the peptide sequence, e.g. a histidine for a glycine, if the resulting peptide sequence is not naturally occurring.

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644. The Examiner can normally be reached by telephone at (703) 305-4441 on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

Effective January 6, 2004, the Examiner's telephone number will be (571) 272-0852.

F. Pierre VanderVegt, Ph.D. *PV*  
Patent Examiner  
November 17, 2003

*Pat J Nolan*  
PATRICK J. NOLAN, PH.D.  
PRIMARY EXAMINER  
*11/21/03*